

## REMARKS

### Allowed Subject Matter

Applicants gratefully acknowledge the Examiner's indication that claims 11, 13, 14, 20, 33 and 51 are allowed.

### Amendments

Claims 42 and 43 are amended to correct obvious typographical errors. Specifically, these claims are amended to depend from claim 40, rather than cancelled claim 41.

Claim 53 is amended to expressly recite the 6-hydroxy-2-(4-hydroxyphenyl)-3-[4-(2-piperidinoethoxy)-benzoyl]benzo[b]thiophene, or the hydrochloride salt thereof.

### Claim Objections

As noted above, claims 42 and 43 are amended to depend from claim 40. Also, claim 53 is amended to recite 6-hydroxy-2-(4-hydroxyphenyl)-3-[4-(2-piperidinoethoxy)-benzoyl]benzo[b]thiophene, or the hydrochloride salt thereof. The Examiner argues that claim 53 and 34 are substantially identical in that 6-hydroxy-2-(4-hydroxyphenyl)-3-[4-(2-piperidinoethoxy)benzoyl]benzo[b]thiophene and Raloxifene are the same.

Withdrawal of the objections is respectfully requested.

### Rejection of claim 35 under 35 USC 112, first paragraph.

Claim 35 is rejected as allegedly lacking written description with respect to the recitation of "or combinations thereof" as to LHRH analogues. Applicants respectfully traversed this rejection.

The recitation of the use of combinations of LHRH analogues is clearly supported by applicants' disclosure. See, e.g., page 3 lines 3-8, wherein it is stated that the invention involves two active ingredients, the first being "an LHRH analogue or a combination of LHRH analogues."

It is respectfully submitted that applicants' disclosure reasonably conveys possession of the subject matter of claim 35, as of the filing date. Withdrawal of the rejection is respectfully requested.

**Rejection of claims 44-47, 52 and 54 under 35 USC 112, first paragraph.**

Claims 44-47, 52 and 54 are rejected as allegedly lacking written description. This rejection is respectfully traversed.

Claim 44, for example, recites a method of inhibiting LHRH analog-induced detrimental side effects due to the administration of an LHRH analog to a patient, wherein the detrimental side effect is reduction in bone density, comprising administering to a patient in need thereof an effective amount of Raloxifene. In the rejection, it is asserted that the disclosure does not provide written description of administering Raloxifene alone. However, applicants respectfully submit that claim 44, and the other rejected claims are clearly supported by the disclosure.

Firstly, applicants' disclosure clearly describes that the LHRH analogue(s) and Raloxifene can be administered separately, and particularly describes the administration of Raloxifene after the administration of LHRH analogue(s). See, e.g., page 3, lines 23-25; page 6, lines 27-29; 13-17; and page 10, line 31-page 11, line 3.

Further, as described in, for example, claim 44, this aspect of the invention relates to inhibiting LHRH analog-induced detrimental side effects due to the administration of an LHRH analog to a patient. Thus, the patient class recited in claim 44 is one to whom an LHRH analog has been or will be administered. Clearly, the patient can not be subject to LHRH analog-induced detrimental side effects unless that patient is administered an LHRH analog.

It is respectfully submitted that applicants' disclosure reasonably conveys possession of the subject matter of claims 44-47, 52 and 54, as of the filing date. Withdrawal of the rejection is respectfully requested.

In view of the above, allowance of the instant application is respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



Brian P. Heaney (Reg. No. 32,542)  
Attorney for Applicants

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.  
Arlington Courthouse Plaza I  
2200 Clarendon Boulevard, Suite 1400  
Arlington, Virginia 22201  
Direct Dial: (703) 812-5308  
Facsimile: (703) 243-6410  
Internet Address: [heaney@mwzb.com](mailto:heaney@mwzb.com)

Filed: **February 6, 2006**